DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable Sherwood L. Boehlert
Chairman
Committee on Science
U.S. House of Representatives
Washington, D.C. 20515-6301

NOV 16 2006

Dear Mr. Chairman:

Thank you for your letter of September 27, 2006, to Dr. Norris Alderson, Associate Commissioner for Science at the Food and Drug Administration (FDA or the Agency), regarding questions submitted for the record by members of the Committee. These questions are follow-up from the Committee's hearing, *Research on Environmental and Safety Impacts of Nanotechnology: What are the Federal Agencies Doing?* We have restated the questions below followed by our answers.

Chairman Boehlert

1. ***The Nanotechnology Environment and Health Implications (NEHI) working group report released on September 21, 2006 says that NEHI's next steps include assessing the existing portfolio of research on environmental and safety impacts of nanotechnology, identifying gaps, and setting research priorities. When will these activities begin and when do you expect them to be completed?***

   The Nanotechnology Environmental and Health Implications Working Group (NEHI) will begin work immediately to address the "next steps" identified in the "Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials" (EHS) report. NEHI is comprised of representatives from the sixteen Federal government agencies that are the most experienced and scientifically qualified in the U.S. Government to consider nanotechnology issues. They all recognize the importance of completing this effort as part of the United States' commitment to realizing the benefits of nanotechnology in a manner that is responsible and that protects health and the environment.

   An important next step is development of a more detailed inventory of the research currently being conducted by the National Nanotechnology Initiative (NNI) funded agencies. This will involve working through the Office of Management and Budget (OMB) to get information so that we can make assessments as to the extent that

current research is addressing the priority work of the five research areas identified in the research needs report.

As for a completion date, NEHI will be in a better position to define this following our receipt and assessment of the information on the current research programs funded under the NNI. We see ourselves moving expeditiously to address the issues and produce a report that is credible and endorsed by all the U.S. Government's agencies represented in NEHI. In the meantime, research related to all five research areas is continuing to be supported in increasing amounts by NNI agencies, including the Environmental Protection Agency (EPA), the National Science Foundation (NSF), the National Institute for Occupational Safety and Health (NIOSH), the National Institutes of Health (NIH), the Department of Defense (DoD), and the Department of Energy (DOE).

We understand the importance of this issue to the Committee and to the United States maintaining its dominance in the development of nanotechnology that is safe for both the U.S consumer and the environment. We believe that the process we are following will enable achievement of these goals.

2. ***In your written testimony, you say that the NEHI working group "will only serve in an advisory capacity" with respect to setting priorities for research on environmental and safety impacts of nanotechnology. In the Q&A during the hearing, Dr. Bement said that the role of setting budget priorities is for the Office of Science and Technology Policy and the Office of Management and Budget. Does the NEHI have any role in the budget setting process of individual agencies or the White House Office's of Science and Technology Policy or Management and Budget? If so, how? If not, should it?***

NEHI plays a valuable role in the budget setting process of those agencies that fund nanotechnology Research and Development (R&D). Through the interagency process, reports like the research needs document represent the consensus of all NEHI member agencies, including those that do not have nanotechnology R&D budgets, and both the Office of Science and Technology Policy (OSTP) and OMB. The work of NEHI provides input to the NNI agencies that fund nanotechnology R&D and through the development of these documents, informs and provides guidance to the respective budget formulation processes for each agency. It is through this process that the NNI agencies that do not have nanotechnology R&D funding, yet that have a mission interest, have an impact on those agencies that have nanotechnology R&D funding. In addition, the NEHI process provides for the development of mutual decisions on the direction of EHS funding in the budget setting process involving the individual agencies and OMB.

3. ***In Dr. Maynard's testimony, he reported that the federal government is spending less on research on environmental and safety issues than the federal government claims it is spending. Why do his estimates differ so greatly from the figures reported by the Administration? What do you need to do to reconcile your figures with his? Are***

detailed accountings of the each agency's spending estimates available? If so, would you please provide them to the Committee.

The funding amounts reported in the NNI Supplement to the President's 2006 and 2007 Budgets for spending on the environmental health and safety (EHS) research to understand the implications of engineered nanoscale materials were obtained from the Office of Management and Budget. Considerable care was exercised by OMB to obtain the best funding numbers from those agencies funding research on this topic. The intentionally restrictive definition developed by the involved agencies and used by OMB was chosen to aid program managers in making clear decisions about which projects and efforts to include in their funding estimates. The definition used by OMB in their request to the agencies was:

> *Research and development on the environmental, health, and safety (EHS) implications of nanotechnology includes efforts whose primary purpose is to understand and address potential risks to health and to the environment posed by this technology. Potential risks encompass those resulting from human, animal, or environmental exposure to nanoproducts—here defined as engineered nanoscale materials, nanostructured materials, or nanotechnology-based devices, and their byproducts.*

With such a restrictive definition, it is doubtful that the Federal government estimates of funding for this research topic are overestimates. In fact, the research topics being proposed by other countries for inclusion under EHS research on nanotechnology include several types of research not included in the definition given above. A key example is research to develop instrumentation and metrology for characterizing the properties of engineered nanoscale materials. Most researchers in this field now recognize that knowledge of the purity of materials used in EHS studies is key to obtaining reproducible results among research studies.

Dr. Maynard's estimates for the Federal government's spending on EHS R&D likely differ from the Federal government's estimates because he did not have full access to funding data from all the agencies involved in this research, and he apparently does not agree with the definition used by the Federal government.

A detailed breakdown—beyond the agency-by-agency data provided in the NNI Supplements to the President's Budgets—of the estimated funding for EHS R&D is not available at this time. As indicated in the "Environmental, Health, and Safety Research Needs for Engineered Nanoscale materials" document, development of a more detailed breakdown of each agency's spending estimates is part of the next steps to be taken by the Federal government as we move forward with our assessment of the research needs in this R&D area.

4. ***In his testimony at the hearing on September 21, Dr. Andrew Maynard from the Wilson Center recommended that the government should ask the Board on Environmental Studies and Toxicology of the National Academies of Science to help develop a long-term***

research agenda and conduct rolling reviews for nanotechnology environmental and safety research. Dr. Maynard also recommended that the government should contract with the Health Effects Institute to manage and/or perform some of the highest priority research. What is your view of Dr. Maynard's recommendations?

The National Academies of Science (NAS) is already tasked to provide a rolling review of the NNI. It would be appropriate to ask the NAS to include the other NAS Boards in the triennial review of NNI. As for the involvement of a third party organization such as Health Effects Institute to conduct nanotechnology health and environment research, this can be an effective means to address specific needs when there is a commitment by both industry and government to provide sustained funding. Without this commitment, it can become unproductive. We are not aware of a nanotechnology industry group that can provide the sustained funding necessary to support this research.

Mr. Gordon

1. ***The EHS research needs report released at the hearing includes several "next steps" (page 10 of the report) for the NEHI working group. What is the estimated timeframe for developing the specific EHS research priorities, evaluating in detail the current federal EHS research portfolio, and performing a gap analysis of current EHS research compared to prioritized needs?***

   The NEHI will begin work immediately to address the "next steps" identified in the "Environmental, Health, and Safety Research Needs for Engineered nanoscale Materials" EHS report. The representatives of the sixteen U.S. Government agencies are the most experienced and scientifically qualified in the U.S. Government to consider nanotechnology issues. They all recognize the importance of completing this effort as part of the United States' commitment to realizing the benefits of nanotechnology in a manner that is responsible and that protects health and the environment.

   An important next step is development of a more detailed inventory of the research currently being conducted by the NNI funded agencies. This will involve working through the OMB to get information so that we can make assessments as to the extent that current research is addressing the priority work of the five research areas identified in the research needs report.

   As for a completion date, we will be in a better position to define this following our receipt and assessment of the information on the current research programs funded under the NNI. We see ourselves moving expeditiously to address the issues and produce a report that is credible and endorsed by all the U.S. Government's agencies represented in NEHI. In the meantime, research related to all five research areas is continuing to be supported in increasing amounts by NNI agencies, including EPA, NSF, NIOSH, NIH, DOD, and DOE.

   We understand the importance of this issue to the Committee and to the United States maintaining its dominance in the development of nanotechnology that is safe for both the U.S consumer and the environment. We believe that the process we are following will enable achievement of these goals.

2. ***In responses to questions at the hearing, the agency witnesses seemed to be saying the current planning/coordinating mechanism for EHS research based on the NEHI working group will be able to produce an EHS research plan or roadmap, consisting of a cross-agency set of specific research priorities, timelines, and associated funding targets broken out by agency. What adjustments are needed to the way NEHI functions or to the way it is staffed to achieve this goal in a timely way?***

   Adjustments are not needed at this time in order for the NEHI to perform a gap analysis and to address any areas that such an analysis might suggest are not being adequately investigated. NEHI members represent sixteen agencies, plus OMB and OSTP. NEHI is supported by the full-time staff of the National Nanotechnology Coordinating Office. The sixteen agencies include agencies that have nanotechnology R&D budgets, as well as those that do not, but that have a mission interest in the subject.

   The NEHI process is significant in terms of the credibility of the products produced. It is not a top-down process. The NEHI process is a collaborative approach to very complex, scientific issues. The collaboration brings to bear the collective expertise of the many agencies involved and provides for their ongoing buy-in—this would not be achieved with a top-down approach. NEHI members also recognize the importance of public input in this process and will develop the means to achieve this objective. We also recognize that the process of obtaining public input adds to the time required.

   NEHI does not produce funding targets for the NNI funded agencies. The NEHI report serves to inform and guide the funding agencies in their respective funding processes, which involve OMB.

   All the NEHI agencies endorse the continuation of the process followed in the development of the NEHI EHS Report. This collaborative process takes time, but the process is sound and in the best interest of the United States in maintaining its dominance in the development of nanoengineered products that are safe to both the U.S consumer and the environment.

3. ***How frequently does the NEHI working group meet (include the schedule of meetings during the past 12 months), and do most members attend meetings (provide the list of current members)?***

   The NEHI Working Group has met on an approximately monthly schedule starting in March 2004. As requested, the meeting schedule for the past 12 months is provided in Enclosure 1. This schedule omits many meetings, both face-to-face and teleconference meetings, by several drafting groups during the six months prior to the publication of the research needs document. Over 75 percent of the NEHI Working Group members normally participate in the meetings. A roster of current members of the NEHI Working Group is provided in Enclosure 2.

4. ***Does the NEHI working group attempt to develop a funding target for the overall EHS research effort under the NNI, as well as funding requirements to achieve specific research goals? What was the role of the NEHI working group in developing the funding estimate for EHS research shown in the FY2007 NNI budget supplement report?***

   The NEHI does not incorporate any funding considerations for EHS research under NNI in any of its report development. NEHI was not involved, as a body, in developing funding estimates for the fiscal year 2007 NNI budget supplement report. Individually, NEHI members, representing their respective agencies on the Nanoscale Science, Engineering and Technology (NSET) Subcommittee, were involved.

   NEHI's process provides for the development of collaborative reports for which there is buy-in during the development process by all the agencies involved. This process also involves OMB, a significant collaborator in the development of the required agency budgets.

5. ***Do you believe the NEHI working group's charter prevents or impedes it from developing budget requirements for achieving EHS research objectives?***

   According to the NEHI charter, one purpose of the working group is to "facilitate the identification, prioritization, and implementation of research and other activities required for the responsible research, development, utilization, and oversight of nanotechnology, including research on methods of life-cycle analysis." Agency budgets must be developed within the larger context of agency missions and priorities. By developing a consensus among NEHI members regarding priorities in the area of EHS research related to nanomaterials, NEHI enables the agencies that fund research related to engineered nanoscale materials to better assess and justify programs in this area within their own organization and to OMB.

6. ***By what means do industry and other interested non-government entities have their views considered by the NEHI working group? Does NEHI hold any open meetings with non-government attendees?***

   In the development of the NEHI EHS Report, other reports were used as information sources. Specifically, a report developed by the chemical and semiconductor industries was used. We also reviewed reports from the Royal Society/Royal Academy of Engineering in the United Kingdom and a report funded by the European commission.

   In past meetings of NEHI, we have had presentations from non-government organizations including the Chemical Abstract Service, March 2004; Intel, Cooperative Boards for Advancing Nanotechnology-EHS, on the group's suggested research targets, October, 2005; and National Research Council's Board on Environmental Studies and Toxicology, March, 2005. We will continue to take advantage of these opportunities as we continue our work.

   All members of NEHI are committed to a more formal process that involves the industry and other interested non-government experts, especially in identifying priority areas. The

development of this process will be a priority for NEHI as we address the next steps identified in the first NEHI document on environment, health, and safety of engineered nanoscale materials.

7. ***Has the NEHI working group attempted to coordinate EHS research funded under the NNI with related research being carried out abroad?***

In furtherance of the efforts of the NSET Subcommittee and NEHI to address the significant issues of nanotechnology standards development, NSET and NEHI members are working in a collaborative manner with representatives from this industry and academia, and with our non-U.S. counterparts. This activity includes participation by NSET and NEHI members on the American National Standards Institute Technical Advisory Group to the International Organisation for Standards Technical Committee on Nanotechnologies, ASTM International E56 Committee, and the Institute of Electrical and Electronics Engineers Committees on Nanotechnology. Additionally, members are collaborating with the U.S. National Committee Technical Advisory Group for the newly formed International Electrotechnical Commissions' technical committee (TC) 113, on Nanotechnology Standardization for Electrical and Electronic Products and Systems.

In addition, the nanotechnology funded agencies, through their normal activities with their foreign counterparts, will collaborate, where appropriate. This would not be an activity of the NEHI, but relevant information would be reported to NEHI.

Recently, the Global Issues in Nanotechnology Working Group (GIN) was chartered as a formal working group under the NSET. Chaired by the State Department, it has representation from the offices of the NNI participating agencies that handle international science and technology issues. The GIN provides review, input, and feedback on documents and other materials for international activities that relate to nanotechnology.

Just getting underway is an international activity within the Organisation for Economic Cooperation and Development. A new working party on manufactured nanomaterials is meeting for the first time this month in London. The main objective will be to address issues related to environmental, health, and safety implications of manufactured (or engineered) nanomaterials, including sharing information on research efforts underway and identifying opportunities for cooperation. The NNI participation in this effort will be coordinated through both the NEHI and the GIN.

8. ***In his testimony at the hearing, Dr. Maynard suggested a mechanism for government to partner with industry to fund EHS research that would support the needs of government in formulating a regulatory framework for nanomaterials and the needs of industry on how to develop nanotechnology safely. The idea is to use the Health Effects Institute model, which studies the health effects of air pollution. What are your views on this suggestion: would this be a workable approach for instituting a government/industry partnership for support of EHS research related to nanotechnology?***

The involvement of a third party organization such as Health Effects Institute to conduct nanotechnology health and environment research can be an effective means to address specific needs when there is a commitment by both industry and government to provide sustained funding. Without this commitment, it can become unproductive. We are not aware of a nanotechnology industry organization that can provide the sustained funding necessary to support this research.

Thank you for your interest in this subject. Please let us know if we can provide any additional information.

Sincerely,

FOR David W. Boyer
Assistant Commissioner
for Legislation

2 Enclosures

cc: HFW 10 (file)
HFW-1 (Dave Boyer)
HFW-14 (Lenahan, Lyons)
HF-32 (Norris Alderson, Rm 14B08)
GCF-1 (John Weiner, Rm 639)

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